

Message

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**From:** Passe, Loraine [Passe.Loraine@epa.gov]  
**Sent:** 4/19/2021 2:32:28 PM  
**To:** Henry, Tala [Henry.Tala@epa.gov]; Le, Madison [Le.Madison@epa.gov]  
**CC:** Fehrenbacher, Cathy [Fehrenbacher.Cathy@epa.gov]  
**Subject:** RE: Letter re: EPA approval of new PFAS under TSCA

I believe it is done – OGC reviewed (covers 2012 to present).

We will get it to RSB.

Loraine Passe  
New Chemicals Division  
Office of Pollution Prevention and Toxics  
U.S. Environmental Protection Agency  
Phone: (202) 564-9064

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**From:** Henry, Tala <Henry.Tala@epa.gov>  
**Sent:** Monday, April 19, 2021 10:00 AM  
**To:** Le, Madison <Le.Madison@epa.gov>  
**Cc:** Fehrenbacher, Cathy <Fehrenbacher.Cathy@epa.gov>; Passe, Loraine <Passe.Loraine@epa.gov>  
**Subject:** RE: Letter re: EPA approval of new PFAS under TSCA

Yes, she is asking Peter & Angela.  
Do you know a 'a big' backlog of FRNs for NC notices?

Also, what is status of the TME FRN? We should get that one to RSB.

Tala R. Henry, Ph.D.  
Deputy Director  
Office of Pollution Prevention & Toxics

T: 202-564-2959  
E: [henry.tala@epa.gov](mailto:henry.tala@epa.gov)

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**From:** Le, Madison <Le.Madison@epa.gov>  
**Sent:** Monday, April 19, 2021 9:59 AM  
**To:** Henry, Tala <Henry.Tala@epa.gov>  
**Cc:** Fehrenbacher, Cathy <Fehrenbacher.Cathy@epa.gov>; Passe, Loraine <Passe.Loraine@epa.gov>  
**Subject:** Fwd: Letter re: EPA approval of new PFAS under TSCA

Tala,

I assume Michal email is for Peter but if She asking NCD a question then can you coordinate with Loraine on this and she can help. Thanks.

Madison

Sent from my iPhone

Begin forwarded message:

**From:** "Freedhoff, Michal" <Freedhoff.Michal@epa.gov>  
**Date:** April 19, 2021 at 9:41:32 AM EDT  
**To:** "Smith, Peterj" <Smith.Peterj@epa.gov>, "Le, Madison" <Le.Madison@epa.gov>, "Henry, Tala" <Henry.Tala@epa.gov>  
**Cc:** "Collazo Reyes, Yvette" <CollazoReyes.Yvette@epa.gov>, "Hofmann, Angela" <Hofmann.Angela@epa.gov>  
**Subject:** RE: Letter re: EPA approval of new PFAS under TSCA

Good morning

Sorry to bump up an old email chain, but the question of the FR delays/backlog just came up on a call related to transparency litigation. Any sense for whether that analysis we chatted about a few weeks ago is doable?

Thanks!  
Michal

Michal Freedhoff, Ph.D.  
Principal Deputy Assistant Administrator  
Office of Chemical Safety and Pollution Prevention  
U.S. Environmental Protection Agency  
[Freedhoff.michal@epa.gov](mailto:Freedhoff.michal@epa.gov)

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**From:** Freedhoff, Michal  
**Sent:** Friday, March 26, 2021 6:32 PM  
**To:** Smith, Peterj <Smith.Peterj@epa.gov>; Le, Madison <Le.Madison@epa.gov>; Henry, Tala <Henry.Tala@epa.gov>  
**Cc:** Collazo Reyes, Yvette <CollazoReyes.Yvette@epa.gov>; Hofmann, Angela <Hofmann.Angela@epa.gov>  
**Subject:** RE: Letter re: EPA approval of new PFAS under TSCA

Thanks

I think next week sometime or the following week would be fine. I'm guessing we will continue to get inquiries.

As to your concern on policy, what we are talking about re PFAS fits squarely within additional changes to the new chemicals approach we have all concluded is not guidance. I think it's fine. 😊

Michal Freedhoff, Ph.D.  
Acting Assistant Administrator  
Office of Chemical Safety and Pollution Prevention  
U.S. Environmental Protection Agency  
[Freedhoff.michal@epa.gov](mailto:Freedhoff.michal@epa.gov)

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**From:** Smith, Peterj <Smith.Peterj@epa.gov>  
**Sent:** Friday, March 26, 2021 5:38 PM  
**To:** Freedhoff, Michal <Freedhoff.Michal@epa.gov>; Le, Madison <Le.Madison@epa.gov>; Henry, Tala <Henry.Tala@epa.gov>  
**Cc:** Collazo Reyes, Yvette <CollazoReyes.Yvette@epa.gov>; Hofmann, Angela <Hofmann.Angela@epa.gov>  
**Subject:** RE: Letter re: EPA approval of new PFAS under TSCA

Thanks Michal!

We'll be happy work the backlog ask. We're a little short on staff next week because of spring break (Angela will also be out). Do you have an ETA in mind for this so that I can focus the team's time and resources to meet your request?

I also need to chime in with some policy development considerations. Policy statements qualify as "guidance documents" under the EPA guidance rule and, even if the guidance rule goes away tomorrow, *may* be "significant regulatory actions" under EO 12866. If EPA finds that the policy would meet definitional criteria for "significance" in EO 12866, the policy statement would need to be developed under the Action Development Process. (The ADP specifically sets forth expectations significant guidance documents, including cross-agency participation in the development effort, the establishment of a docket, and a public comment opportunity.) OP would also notify OMB that the policy statement is significant and subject to interagency review.

I am not suggesting whether the policy statement would need extra process. However, given recent IG attention on ADP adherence, I just want to make sure that (1) the OCSPP leadership team approaches this with eyes open, and (2) RSB has sufficient information to support the leadership team's determination if our counterparts across EPA as well as at OMB, SBA/Office of Advocacy, and other agencies start asking questions and raising any process concerns.

Best,  
Peter

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**From:** Freedhoff, Michal <Freedhoff.Michal@epa.gov>  
**Sent:** Friday, March 26, 2021 3:18 PM  
**To:** Le, Madison <Le.Madison@epa.gov>; Henry, Tala <Henry.Tala@epa.gov>  
**Cc:** Collazo Reyes, Yvette <CollazoReyes.Yvette@epa.gov>; Smith, Peterj <Smith.Peterj@epa.gov>  
**Subject:** RE: Letter re: EPA approval of new PFAS under TSCA

Thank you – totally understood that the section 4 rule would be a longer term endeavor, and could be wrapped into other PFAS/other information gathering activities we've been discussing.

I wonder whether the Ex. 5 Deliberative Process (DP)

## Ex. 5 Deliberative Process (DP)

But I'm also copying Peter here because I think it could be Ex. 5 Deliberative Process (DP)

## Ex. 5 Deliberative Process (DP)

# Ex. 5 Deliberative Process (DP)

Thank you  
Michal

Michal Freedhoff, Ph.D.  
Acting Assistant Administrator  
Office of Chemical Safety and Pollution Prevention  
U.S. Environmental Protection Agency  
[Freedhoff.Michal@epa.gov](mailto:Freedhoff.Michal@epa.gov)

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**From:** Le, Madison <[Le.Madison@epa.gov](mailto:Le.Madison@epa.gov)>  
**Sent:** Friday, March 26, 2021 2:10 PM  
**To:** Henry, Tala <[Henry.Tala@epa.gov](mailto:Henry.Tala@epa.gov)>; Freedhoff, Michal <[Freedhoff.Michal@epa.gov](mailto:Freedhoff.Michal@epa.gov)>  
**Cc:** Collazo Reyes, Yvette <[CollazoReyes.Yvette@epa.gov](mailto:CollazoReyes.Yvette@epa.gov)>  
**Subject:** RE: Letter re: EPA approval of new PFAS under TSCA

Tala - The letter seems to be referencing two submissions (P-18-0058 and SN-17-0011) which were issued in January 2020 (which was over a year ago, and not “recent” per se). Also, these two chemicals do not meet our working definition of PFAS (i.e., doesn’t have 2 consecutive fluorinated carbons), and one is considered to have low persistence and bioaccumulation. I’ll send more details on the CBI side. I’ll have the team start prepping the draft response and work with OGC on it.

Michal – Tala is right that we have multi-facet plan, and are executing on the low hanging fruit right now. Below is an update on the near and long-term options we discussed at the last 2/22 briefing on NC PFAS policy approaches for PFAS LVEs and PMNs.

## LVEs

- 2 LVEs pending – we have denied one and prepping the denials for other three. We have good legal and technical standing to deny these LVEs (per
- 700 previously granted LVEs – we are prepared to start contacting companies to see if they will voluntary withdraw their LVEs (we’ve had some success in the past in 2018 effort, and we know of a one company connected to the Solvay issue that plans with withdraw 2 LVEs by this summer). We are still prepping what a “stewardship” program could look like to get more companies to withdraw and prioritize this effort,
- **Draft policy statement** on discontinuing PFAS LVEs: Ex. 5 Deliberative Process (DP)

# Ex. 5 Deliberative Process (DP)

## PMNs/SNUNs

- 24 PMNs and 2 SNUNs pending – we have not completed these cases but we expect to issue orders (with testing) and potentially limiting/prohibiting manufacturer depending on the outcome of the risk assessment
  - One case is C8, handful are PF ethers, the rest are short chain PFC
  - Most are used for coatings or as intermediate to other PFAS
  - Three of the LVEs were submitted in 2020 and one in 2021

- The PMNs and SNUNs range from recent submissions to cases under suspension for “rework” for many years

## Ex. 5 Deliberative Process (DP)

- **Policy statement** (to be developed) – I’m not aware of any policy statements drafted, but we

## Ex. 5 Deliberative Process (DP)

Madison H. Le  
Division Director  
New Chemicals Division  
USEPA/OCSP/OPPT  
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Cell: 202-507-3062

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**From:** Henry, Tala <[Henry.Tala@epa.gov](mailto:Henry.Tala@epa.gov)>  
**Sent:** Friday, March 26, 2021 1:59 PM  
**To:** Freedhoff, Michal <[Freedhoff.Michal@epa.gov](mailto:Freedhoff.Michal@epa.gov)>; Le, Madison <[Le.Madison@epa.gov](mailto:Le.Madison@epa.gov)>  
**Cc:** Collazo Reyes, Yvette <[CollazoReyes.Yvette@epa.gov](mailto:CollazoReyes.Yvette@epa.gov)>  
**Subject:** RE: Letter re: EPA approval of new PFAS under TSCA

As with the overall approach to changes, (i.e., incremental, starting with the most straight-forward, easiest to implement), there are multiple facets to the plan.

NCD is already implementing the LVEs approach as LVE PFAS come in...not sure if any have since we landed on the approach. Also, NCD has begun to reach out to those with older (long-chain) LVEs to suggest ‘withdrawing’. Similarly, I believe new PMNs would be subject to the new thinking re: COs.

The ‘bigger ticket’ items, like revoking prior granted LVEs and writing a Section 4 rule require additional resourcing and we have to plan those out within that context.

We do have a handful of cases, which have specific ‘circumstances’/long-standing history around them, which we are ready to have a discussion with you about...planned on working into an upcoming OPPT General or Wed General with you.

Madison: Re: the letter – I did not look up the specific notice the letter writers were referencing, but realize it also could have been SNUR following 5e Orders.

Tala R. Henry, Ph.D.  
Deputy Director  
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**From:** Freedhoff, Michal <[Freedhoff.Michal@epa.gov](mailto:Freedhoff.Michal@epa.gov)>  
**Sent:** Friday, March 26, 2021 1:30 PM

**To:** Henry, Tala <[Henry.Tala@epa.gov](mailto:Henry.Tala@epa.gov)>; Le, Madison <[Le.Madison@epa.gov](mailto:Le.Madison@epa.gov)>

**Cc:** Collazo Reyes, Yvette <[CollazoReyes.Yvette@epa.gov](mailto:CollazoReyes.Yvette@epa.gov)>

**Subject:** RE: Letter re: EPA approval of new PFAS under TSCA

Thanks Tala

How close would you all say we are to landing on a new chemicals PFAS policy approach?

Michal

Michal Freedhoff, Ph.D.

Acting Assistant Administrator

Office of Chemical Safety and Pollution Prevention

U.S. Environmental Protection Agency

[Freedhoff.michal@epa.gov](mailto:Freedhoff.michal@epa.gov)

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**From:** Henry, Tala <[Henry.Tala@epa.gov](mailto:Henry.Tala@epa.gov)>

**Sent:** Friday, March 26, 2021 1:25 PM

**To:** Le, Madison <[Le.Madison@epa.gov](mailto:Le.Madison@epa.gov)>

**Cc:** Collazo Reyes, Yvette <[CollazoReyes.Yvette@epa.gov](mailto:CollazoReyes.Yvette@epa.gov)>; Freedhoff, Michal

<[Freedhoff.Michal@epa.gov](mailto:Freedhoff.Michal@epa.gov)>

**Subject:** FW: Letter re: EPA approval of new PFAS under TSCA

Madison,

Many/most/all of the signers of the letter are litigants in the PFAS Section 21 Petition.

Please have you team prepare a Ex. 5 Deliberative Process (DP)

## Ex. 5 Deliberative Process (DP)

Thank you.

Tala R. Henry, Ph.D.

Deputy Director

Office of Pollution Prevention & Toxics

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**From:** Jonathan Kalmuss-Katz <[jkalmusskatz@earthjustice.org](mailto:jkalmusskatz@earthjustice.org)>

**Sent:** Friday, March 26, 2021 12:25 PM

**To:** Freedhoff, Michal <[Freedhoff.Michal@epa.gov](mailto:Freedhoff.Michal@epa.gov)>

**Cc:** Tyler, Tom <[Tyler.Tom@epa.gov](mailto:Tyler.Tom@epa.gov)>; Le, Madison <[Le.Madison@epa.gov](mailto:Le.Madison@epa.gov)>; Henry, Tala

<[Henry.Tala@epa.gov](mailto:Henry.Tala@epa.gov)>; Collazo Reyes, Yvette <[CollazoReyes.Yvette@epa.gov](mailto:CollazoReyes.Yvette@epa.gov)>

**Subject:** Letter re: EPA approval of new PFAS under TSCA

Dear Assistant Administrator Freedhoff:

The 18 undersigned organizations submit this letter objecting to EPA's approval of new per- and polyfluoroalkyl substances (PFAS) and new uses of previously approved PFAS, as reflected most recently in EPA's March 10, 2021 Federal Register publication of "Certain New Chemicals or Significant New Uses; Statements of Findings for January through December 2020." For the reasons set forth in the letter, we urge EPA to stop approving PFAS under TSCA Section 5 and to address the flaws in EPA's new chemical review process that have facilitated the approval of prior PFAS.

If you have any questions about the attached letter, please don't hesitate to contact me.

Respectfully submitted,

Advance Carolina  
Center for Environmental Health  
Clean Cape Fear  
Clean Haw River  
Clean and Healthy New York  
Defend Our Health  
Democracy Green  
Earthjustice  
Environmental Defense Fund  
Environmental Working Group  
GreenCAPE  
Merrimack Citizens for Clean Water  
Mothers For Safe Air & Safe Water Force  
Natural Resources Defense Council  
Safer Chemicals Healthy Families  
Sierra Club  
Toxic Free North Carolina  
Union of Concerned Scientists

Jonathan Kalmuss-Katz  
Staff Attorney  
Earthjustice Northeast Office  
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Pronouns: he/him/his  
[earthjustice.org](http://earthjustice.org)



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